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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,923	06/25/2001	Alain Sanson	205399USOXP	8658

22850 7590 12/23/2004

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,923	SANSON ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/14/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) 116-121, 126 and 129-142 is/are allowed.
- 6) ☒ Claim(s) 13-16, 45, 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 13-16,19,24,45,50,60,65,69,74,80,84,89,95,101,107,112 and 116-142.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 19,24,50,60,65,74,80,84,89,95,101,107,112,122-125,127 and 128.

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DETAILED ACTION

1. This Office Action is in response to Paper filed 14 October 2004. Claims 1-12, 17-18, 20-23, 25-44, 46-49, 51-59, 61-64, 66-68, 70-73, 75-79, 81-83, 85-88, 90-94, 96-100, 102-106, 108-111, 113-115 have been canceled. Applicant's amendment of claims 13-16, 19, 24, 45, 50, 69, 107, and 112 is acknowledged. Applicant's addition of new claims 116-142 is acknowledged. Claims 13-16, 19, 24, 45, 50, 60, 65, 69, 74, 80, 84, 89, 95, 101, 107, 112 and 116-142 are pending. Claims 19, 24, 50, 60, 65, 74, 80, 84, 89, 95, 101, 107, 112 have been previously withdrawn from consideration.
2. Claims 122-125 and 127-128 are withdrawn from consideration as the claims are directed to the inventions of Groups III and VI, respectively.
3. Claims 13-16, 45, 69, 116-121, 126 and 129-142 are under examination.

Withdrawal of Objections and Rejections

4. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16, 45, and 69 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for all cyclic peptides of formula VII where M is 1 to 100. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming a genus of cyclic polypeptides comprising the structure defined as formula VII. The nature of the invention involves the ability to make and use the cyclic polypeptides of formula VII where M is 1 to 100. There is no absolute predictability even in view of the seemingly high level of skill in the art that a cyclic polypeptide would maintain stability and could exist as a cyclic peptide given the size of the ring where, for example, M is equal to 100 amino acids. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any that such a polypeptide could exist in cyclic form. The instant specification does not give any guidance as to the full range of cyclic polypeptides nor to any specific cyclic polypeptide. In order to practice the claimed invention, one skilled in the art would have to speculate which cyclic polypeptides could in fact exist and possess the specific properties necessary to practice the scope of the invention. The number of possible unenabled embodiments embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the invention

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is not enabled where M is 1 to 100 because the metes and bounds of the invention cannot be achieved.

Conclusion

6. Claims 116-121, 126 and 129-142 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959.

The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

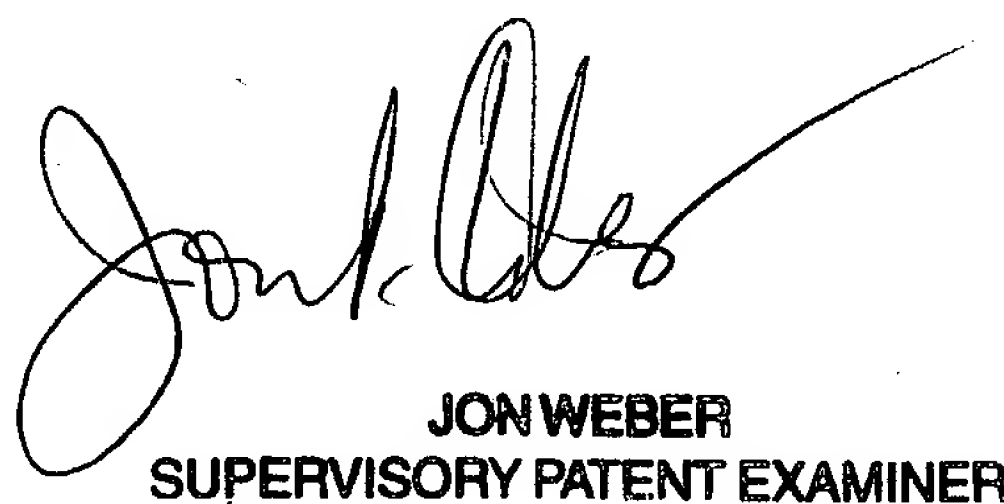
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

December 21, 2004

SKS



JON WEBER
SUPERVISORY PATENT EXAMINER